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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/464,303	12/15/1999	GREGORY L. STAHL	B0801/7156	7348

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HELEN C LOCKHART  
WOLF GREENFIELD & SACKS P C  
600 ATLANTIC AVENUE  
BOSTON, MA 02210

EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 10/15/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/464,303

Applicant(s)

STAHL ET AL.

Examiner

Amy M. DeCloux

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 September 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-34 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 36-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 30-32 is/are allowed.
- 6) ☐ Claim(s) 18-29, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 December 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### DETAILED ACTION

Applicant's after-final amendment filed 9-16-02 (Paper No.15) is acknowledged and has been entered.

Applicant's request to withdraw the finality of the office action mailed 5-7-02 (Paper No.13), is based on the contention that the new rejections applied to amended base claim 18, which was amended to incorporate a limitation of a co-pending dependent claim, should have been applied to the dependent claim in the first office action. And therefore the finality was not necessitated by applicant's amendment. However, the examiner points out that the exact recitation of said limitation from the dependent claim was not exactly incorporated into the independent claim because "MBL binding CDR3<sub>1</sub> region or a functional variant thereof" is not the same as "MBL binding CDR3 region or a functional variant thereof", as evidenced by the 112 first new matter rejection which was applied upon amended claim 18. Therefore, the claims presented after the first office action were not the same as the claims examined before the first office action.

However, upon reconsideration, the finality of the office action mailed 5-7-02 (Paper No.13), has been withdrawn.

### *Drawings*

Note. **As noted in the office action mailed 5-7-02 and 7-31-01**, Formal drawings and/or photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the PTO-948 form attached to the office action mailed 7-31-01 (Paper No. 9).

#### A). Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

#### B) Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

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**C) Timing of Corrections**

**Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.**

***Claim Rejections - 35 USC § 112***

In view of Applicant's after-final amendment the 112 first paragraph new matter rejection has been withdrawn. Also the 112 first paragraph written description and enablement rejections of claims 30-32 have been withdrawn. However these 112 first paragraph written description and enablement rejections of claims 18-29 and 33-34 have been maintained.

**MAINTAINED** Claims 18-29 and 33-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

***Response to Arguments***

Applicant's arguments filed 9-16-02 (Paper No. 15) have been fully considered but they are not persuasive. Applicant traverses on the grounds that functional variants of the claimed core peptide that functions in MBL binding and inhibition, do not encompass an indeterminate number of amino acids and that the specification provides adequate guidance for identifying functional variants. However, without further description from the specification, one would not know if they were in possession of a species of the genus of functional variants of the recited core protein because the specification does not provide a structural basis for the location, or the number or the type of substitutions, additions and deletions in the core peptide that could be made and still function as an MBL inhibitor. It is noted that though the claimed invention is directed to polypeptides and not cDNA, the principle of the following still holds for said polypeptides: a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus, or of a recitation of structural features common to the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Applicant further contends that it is known how to determine the sequence of a fragment of an antibody, synthesize and or isolate a peptide, make functional variants and assess the ability of the peptides to perform a desired function. However, Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision.

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**MAINTAINED** Claims 18-29 and 33-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising an MBL inhibitor comprising an antibody produced by the hybridoma cell lines 2A9, 3F8 and hMBL1.2, does not reasonably provide enablement for the broader recitation of a composition comprising an MBL inhibitor comprising any peptide comprising an MBL CDR3 region of said antibodies, or any functional derivative thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

### ***Response to Arguments***

Applicant traverses the rejection on the grounds that one of skill would know how to make a peptide comprising one of the three CDR3 regions of the antibodies produced from the deposited hybridomas. However, the examiner notes that each hybridoma has two CDR3 regions (one from the heavy Immunoglobulin chain and one from the light immunoglobulin chain) so the instant claims encompass six CDR3 regions not three. Applicant further contends that one of skill would be able to determine whether or not a peptide possessed the desired functional characteristics. It is noted that the specification does not exemplify the ability of any peptide consisting of one of the six CDR3 peptides as inhibiting LCP complement activation. Applicant contends that both the specification and Janeway teach the importance of the CDR3 region for antibody specificity with which the examiner agrees. However, the examiner notes that both the specification (page 18) and Janeway teach that that antibody specificity of an antibody is determined by the CDR1, CDR2 and CDR3 regions of the heavy and light chains.

Applicant argues that Abaza does not address the the predictability of amino acid substitutions in an MBL binding peptide comprising a CDR3 region because Abaza teaches amino acid changes in an antigen outside of its epitope. However, the fact that an amino acid change outside the antibody-antigen binding site can effect the ability of an antibody-antigen to bind to each other without even changing any of the amino acids within the antibody-antigen binding site further, denotes the unpredictability of changing amino acids within the antigen antibody binding site.

### ***Allowable Subject Matter***

Claims 30-32 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

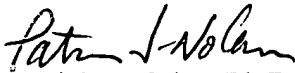
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
October 10, 2002

  
Patrick J. Nolan, Ph.D.  
Primary Patent Examiner,  
Group 1640